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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,694	09/18/2008	Michael Agus	2099.00040	1821

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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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08/04/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/575,694

Applicant(s)

AGUS, MICHAEL

Examiner

PATRICIA MALLARI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 1 and 7 are objected to because of the following informalities:

On line 2 of claim 1, "at least one analyte" should be deleted.

On line 2 of claim 7, "sensor" should be replaced with "sensor means" since "sensor means" is consistently used throughout the claims and "sensor" alone is not.

On line 3 of claim 7, "analytes" should be replaced with "analyte".

On line 4 of claim 7, "amounts" should be replaced with "amount". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-16 are rejected under 35 U.S.C. 101 because based upon consideration of all of the relevant factors with respect to the claim as a whole, claim(s) 11-16 are held to claim an abstract idea, and is/are therefore rejected as ineligible subject matter under 35 U.S.C. 101. The rationale for this finding is explained below:

The claims fail to recite a machine or physical transformation in a significant step of the method and fail to otherwise set forth a statutory method claim.

This rejection may be overcome by positively reciting a machine used in a significant step (i.e. not a data gathering or data outputting step) of the claim, commensurate with the applicants' original disclosure.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a device but fails to set forth any structure for such device, thereby rendering the claim indefinite. Applicants should clarify.

The language of claims 2-10 makes it unclear as to whether a method, as indicated by the preamble ("the use of the analyte monitoring device") or an apparatus, as indicated by the independent claim 1 and the language following the preamble (e.g. "further including monitoring means" in claim 7) is being claimed. Applicants should clarify.

Each of claims 2-6 recites "said sensor means". There is insufficient antecedent basis in the claims or in independent claim 1, upon which each of claims 2-6 depends, for the limitations. Applicants should clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 4-16 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4633878 to Bombardieri. Regarding claims 1 and 11, Bombardieri teaches an *in vivo* analyte monitoring device for use in continuously monitoring the presence of at least one analyte within a bodily fluid bypass flow path (see entire document, especially fig. 1; col. 3, lines 7-21 of Bombardieri).

Regarding claim 2, a sensor means of the device provides continuous real-time monitoring (see entire document, especially col. 1, lines 33-35 of Bombardieri).

Regarding claim 4, the sensor means is an electrochemical sensor (see entire document, especially col. 2, lines 34-40 of Bombardieri).

Regarding claim 5, the sensor means can monitor at least glucose (see entire document, especially col. 2, line 33 of Bombardieri).

Regarding claim 6, the sensor means quantitates (quantifies) the amount of analyte detected (see entire document, especially col. 2, lines 33-51 of Bombardieri).

Regarding claims 7 and 12, monitoring means operatively connected to the sensor means monitors the amount of analyte detected by the sensor means and compares the detected amount to set norms (see entire document, especially claim 5 of Bombardieri). The language “monitoring means . . . for monitoring the amount of

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analytes . . .” meets the three pronged analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6th paragraph. Bombardieri discloses the corresponding structure set forth in the applicants’ specification or an equivalent thereof.

Regarding claims 8, 9, and 12-15 responding means 7, 8, which includes administration means for administering at least one compound to the patient, operatively communicates with the monitoring means for responding to the detected amount of analyte outside of the norms in order to bring the amount detected back into the range of the set norms (see entire document, especially col. 2, lines 57-66; claims 4 and 5 of Bombardieri). The language “responding means . . .for responding to detected amount of analytes . . . “ and “administration means for administering to the patient at least one compound . . .” meet the three pronged analysis set forth in MPEP 2181, thereby invoking 35 U.S.C. 112, 6th paragraph. Bombardieri discloses the corresponding structure set forth in the applicants’ specification or an equivalent thereof.

With further regard to claim 15, the responding step includes administering insulin to the patient (see entire document, especially col. 2, lines 57-66; claim 5 of Bombardieri).

Regarding claim 10, the bypass flow path is a continuous hemodialysis or hemofiltration circuit (see entire document, especially col. 2, lines 1-10; claim 1 of Bombardieri). It is further noted that the claim merely requires that the device be capable of use ("for use") in one of the claimed circuit, wherein the device of Bombardieri is certainly capable of such use.

Regarding claim 16, monitoring includes monitoring changes in the amount of analytes (see entire document, especially claims 4 and 5 of Bombardieri).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardier, as applied to claims 1, 2, and 4-16 above, and further in view of US 4240438 to Updike et al. Updike teaches an *in vivo* analyte monitoring device for use in continuously monitoring the presence of at least one analyte within a bodily fluid bypass flow path (see entire document, especially fig. 1 of Updike), wherein the sensor means of the device provides periodic real-time monitoring (see entire document, especially col. 1, lines 61-68; col. 2, lines 27-36 of Updike). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the periodic monitoring of Updike in place of the continuous monitoring of Bombardieri as it would merely be the substitution of one known timing for monitoring for another and wherein an interval of 2 or 2.5 minutes is shown to be a sufficient monitoring interval for monitoring glucose.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Each of US 3512517 to Hall et al., US 4493692 to Reed, US 6128519 to Say, and US 7458033 to Van Antwerp et al. teaches an *in vivo* analyte-monitoring device for use in continuously monitoring at least one analyte within a bodily fluid bypass flow path.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 9:30 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735